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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,024	09/27/2004	Sophi Anne Michele Bozonnet	2121-0183PUS1	3430

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EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	PAPER NUMBER
1652	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/27/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/27/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/509,024	BOZONNET ET AL.	
	Examiner	Art Unit	
	Christian L. Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *1-8 and 19-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of Invention 2 (claims 9-18) in the reply filed on 02/06/07 is acknowledged. Claims 1-8 and 19-26 are withdrawn from further consideration as drawn to a non-elected invention.

2. Claims 9-18 are under consideration in this Office Action.

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

4. The information disclosure statement filed 09/27/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 9-12, 17, 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9 and 10 recite the phrase "having at least 50%, preferably at least 80% identity" which renders the claim vague and indefinite because the meaning of the phrase is not known. It is not clear if the nucleic acid is actually at least 50% or at least 80% identity with SEQ ID NO: 3. Appropriate correction is requested.

Claim 10 recites the phrase "the latter preferably being located between the two sequences in a)" which renders the claim vague and indefinite because the meaning of the phrase is not known. It is not clear if the nucleotide sequence encoding the glucan binding domain is indeed "between the two sequences in a)". Appropriate correction is requested.

Claim 11 recites the phrase "a sequence hybridizing a) or b) under stringent conditions" which renders the claim vague and indefinite because the meaning of the phrase is not known and not defined in the specification. Appropriate correction is requested.

Claim 12 recites the phrase "constituted by SEQ ID NO: 4 or its complementary strand" which is vague and indefinite since it is not clear if the claimed isolated nucleic acid comprises or consists of SEQ ID NO: 4. Appropriate correction is requested.

Claim 12 recites the phrase "deduced from the degeneracy of the genetic code" which is vague and indefinite since the specific nucleotide sequence is not known and defined by the specification. Clarification is requested.

Claims 17 and 18 recite the phrase "A transformed cell". There is insufficient antecedent basis for this limitation in the claims. Appropriate correction is requested.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 9-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nuclei acid consisting of SEQ ID NO: 4 encoding a dextransucrase that can form that can form dextrans having α(1→2) linkages from saccharose, α-D-fluoroglucose, para-nitrophenyl-α-D-glucopyranoside, α-D-glucopyranoside-α-D-sorbofuranoside or 4-O-α-D-galactopyranosylsucrose; does not reasonably provide enablement for any other embodiment as recited in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any isolated nucleic acid encoding an enzyme with glycosyltransferase activity comprising at least one nucleotide sequence encoding a catalytic domain having at least 50% or 80% identity with SEQ ID NO: 3, any isolated nucleic acid encoding an enzyme with glycosyltransferase activity having at least 80% identity to SEQ ID NO: 4, and any isolated nucleic acid encoding an enzyme with glycosyltransferase activity having at least 80% identity to the sequence encoding a dextransucrase expressed by a plasmid deposited with accession number I-2649.

The specification provides guidance and working example for of SEQ ID NO: 4 encoding a dextransucrase that can form that can form dextrans having α(1→2) linkages from saccharose, α-D-fluoroglucose, para-nitrophenyl-α-D-glucopyranoside, α-D-glucopyranoside-α-D-

sorbofuranoside or 4-O-α-D-galactopyranosylsucrose.

However, the specification does not provide guidance, working examples, or prediction for making and/or using any isolated nucleic acid encoding an enzyme with glycosyltransferase activity comprising at least one nucleotide sequence encoding a catalytic domain having at least 50% or 80% identity with SEQ ID NO: 3, any isolated nucleic acid encoding an enzyme with glycosyltransferase activity having at least 80% identity to SEQ ID NO: 4, and any isolated nucleic acid encoding an enzyme with glycosyltransferase activity having at least 80% identity to the sequence encoding a dextransucrase expressed by a plasmid deposited with accession number I-2649.

Thus, an undue amount of trial and error experimentation must be preformed where such experimentation involves searching and screening a vast number of biological sources for the recited nucleic acids. Trial and error experimentation also includes searching and screening for specific nucleotide changes (nucleotide deletion, insertion, addition, substitutions, and combinations thereof) in SEQ ID NO: 3 or SEQ ID NO: 4 that will result in a nucleic acid that will still encode a functional enzyme. General teaching regarding screening and searching for the claimed invention is not guidance for making the claimed invention.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and/or use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, such as information regarding the specific nucleotides to change in SEQ ID NO: 3 or SEQ ID NO: 4, the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

Furthermore, with regard to claim 11, directed to a polynucleotide sequence that hybridizes to the disclosed sequences, Applicants have not sufficiently defined the conditions under which the hybridizations are to take place. Nucleic acid hybridization assays are extremely sensitive to the conditions in which they are performed. The buffer composition, pH, temperature, length of time, salt concentrations, quality and source of template nucleic acid, are all variables which determine the reproducibility of a given hybridization experiment. Given the unpredictability of the art and the nature of hybridization experiments in general, it is not sufficient to merely cite hybridization without a clear and explicit recitation of the conditions associated with the hybridization. For example, the definition of stringency as it pertains to hybridization conditions is subject to interpretation and is different from laboratory to laboratory. Therefore, without a clear and explicit recitation of the conditions which were actually used by Applicants in isolating the claimed polynucleotides which hybridize to the disclosed sequences, the skilled artisan would not be able to practice the claimed invention and would not be reasonably apprised of the metes and bounds of the claimed invention. Without such guidance, the experimentation left to those skilled in the art is undue. Including in claim 11 the exact nature of the hybridization conditions used to isolate the claimed polynucleotides would aid in overcoming this portion of the rejection.

Regarding claims 13 and 18, it is apparent that the plasmid of claim 13 and *E.coli* strain of claim 18 are required to practice the claimed invention. As such the recited plasmid and

E.coli strain must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 USC § 112, first paragraph, may be satisfied by a deposit of the plasmid and *E.coli* strain.

The process disclosed in the specification to make the plasmid and *E.coli* strain does not appear to be repeatable. The nucleotide sequences of the plasmid vector are not fully disclosed, nor have all the nucleotide sequences required for their construction been shown to be biblically known and freely available. The specification does not disclose a repeatable process to obtain the plasmid and *E.coli* strain and it is not apparent if the nucleotide sequences are readily available to the public. It is not apparent if the source materials to make the plasmid and *E.coli* strain are both known and readily available to the public.

Applicants' referral to deposit numbers I-2649 is noted but is considered insufficient assurance that all of the conditions of 37 CFR 1.801-1.809 have been met since there is no indication in the specification as to public availability.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicant, or a statement by an attorney of record over his/her signature and registration number, stating that the specific microorganism has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809 and MPEP 2402-2411.05, the applicant may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his/her signature and registration number, showing that:

(1) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(2) all restriction upon availability to the public will be irrevocably removed upon granting of the patent;

(3) the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

(4) the deposit will be replaced if it should ever become inviable.

Conclusion

9. No claim is allowed.

10. The following reference made of record and not relied upon is considered pertinent to applicant's disclosure: Fabre et al. (J Bacteriol. 2005 Jan;187(1):296-303) teach the two catalytic domains of DSR-E dextransucrose and their involvement in formation of branched dextran.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The

examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF

TEKCHAND SAIDHA
PRIMARY EXAMINER